DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

NOV 22 2004

Joseph D. Artiss, Ph.D.
ArtJen Complexus Inc.
510 Westcourt Place
251 Goyeau Street
Windsor, Ontario N9E 2T2 Canada

Dear Dr. Artiss:

This is to inform you that the notification, dated August 27, 2004, you submitted pursuant to 21 U.S.C. 350b(a)(2)(section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) was filed by the Food and Drug Administration (FDA) on September 8, 2004. Your notification concerns the substance "α-cyclodextrin" that you intend to market as a dietary supplement under the trade name FBCx™.

According to the notification, "The supplement will be in the form of tablets and/or chewable tablets. Each tablet will contain 1.0 g of α-cyclodextrin. Chewable tablets may contain either 1.0 g or 2.0 g of α-cyclodextrin." The notification further states, "it is recommended that two 1.0 g tablets or chewable tablets or one 2.0 g chewable tablet be consumed within one hour, before, after, or during the consumption of a fat containing meal."

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement containing a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under section 350b(a)(2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is considered to be adulterated under 21 U.S.C. 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

FDA has carefully considered the information in your submission, and the agency has concerns about the evidence on which you rely to support your conclusion that a dietary supplement containing "α-cyclodextrin" will reasonably be expected to be safe.

Although your notification included a general description of a manufacturing process for "α-cyclodextrin", your notification does not contain any information about the product specification of "α-cyclodextrin". The notification contained a summary of the 2001 Joint Expert Committee on Food Additives (JEFCA)[1] Report. According to page 2 of the 2001 JEFCA Report summary, there is no established ADI for α-cyclodextrin's "use as a carrier and stabilizer for flavours, colours, and sweetners, as a water-solubilizer for fatty acids and certain vitamins, as a flavour modifier in soya milk, and as an adsorbent in confectionery." JEFCA did not consider exposure from dietary supplements when making their conclusions regarding the exposure levels and safety of a food additive or contaminant. Therefore, FDA cannot make an assessment of safety for "α-cyclodextrin" use as a dietary supplement because your notification fails to provide adequate identity information to characterize the specific "α-cyclodextrin" you intend to market in your dietary supplement.

Moreover, you state in your notification that your product, ""α-cyclodextrin" is affirmed as a Generally Recognized As Safe (GRAS) substance under the conditions of its intended use in foods." However, your proposed "intended use" of "α-cyclodextrin" is as a dietary supplement and not as a food additive. Please note that the Code of Federal Regulations (CFR) 170.30(i) states that "If a substance is affirmed as GRAS... with no limitation other than good manufacturing practice, it shall be regarded as GRAS if its conditions of use are not significantly different from those reported in the regulation as the basis on which the GRAS status of the substance was affirmed. If the conditions of use are significantly different, such use of the substance may not be GRAS."

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that your product containing "α-cyclodextrin", when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe. Therefore, your product may be adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

Your notification will be kept confidential for 90 days after the filing date of September 8, 2004 . After the 90-day date, the notification will be placed on public display at FDA's Division of

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1. Joint FAO/WHO Expert Committee on Food Additives, Fifty-seventh meeting, Rome, 5-14 June 2001.

Docket Management in docket number 95S-0316. Prior to that date, you may wish to identify in writing specifically what information you believe is proprietary, trade secret or otherwise confidential for FDA's consideration.

If you have any further questions concerning this matter, please contact Linda S. Pellicore, Ph.D., at (301) 436-2375.

Sincerely yours,

Linda S. Pellicore

for Susan J. Walker, M.D.
Director
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and Dietary Supplements
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